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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/606,808

Examiner

Ashwin Mehta

Applicant(s)

LARKINS ET AL.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 4-6 is/are allowed.
- 6) ☒ Claim(s) 2,3 and 7-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The finality of the Office action mailed 02 December 2002 is withdrawn, and the following Non-Final Office action is set forth.

#### ***Claim Objections***

2. Claim 24 remains objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form.

Claim 24 attempts to limit the hybrid plant of claim 23 by requiring it to be an F<sub>1</sub> hybrid corn plant. However, the plant of claim 23 is the first generation progeny of the cross of two distinct inbred plants, and therefore is an F<sub>1</sub> hybrid plant. Claims 23 and 24 encompass the same plants.

In the paper received 25 September 2002, Applicants argued that claims 23 and 24 have been amended, and that claim 23 is not limited to a hybrid corn plant whereas claim 24 is (response, page 3, 2<sup>nd</sup> full paragraph). However, claim 23 is still limited to an F<sub>1</sub> hybrid corn plant. The corn plant of claim 23 is produced by growing seed that is produced by crossing inbred corn plant LIZL5 with another, distinct inbred corn plant. The corn plant of claim 23 is an F<sub>1</sub> hybrid.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1638

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 3, and 7-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2: the recitation "further defined as an essentially homogenous population of inbred corn seed" renders the claim indefinite. The claim broadens the scope of its parent claim. Claim 1 only encompasses seed of corn plant LIZL5. The recitation in claim 2, however, attempts to limit claim 1 by indicating that the seed is an "essentially homogeneous population of inbred corn seed." Lines 17-22 on page 5 of the specification indicate that the inbred seed can form less than 100% of an essentially homogenous population. Claim 2, then, encompasses seed other than seed of corn plant LIZL5.

In claim 3: the recitation "further defined as essentially free from hybrid seed" renders the claim indefinite, for reasons similar to the rejection of claim 2. The recitation "essentially free" indicates that claim 3 encompasses seed other than LIZL5. Further, claim 1 does not make any mention of hybrid seed.

In claim 7: the recitation "An essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5" in lines 1-2 renders the claim indefinite. LIZL5 seed can only produce LIZL5 plants. The claim does not mention any other type of seed. The population can therefore only consist of LIZL5 plants. It is then not clear why the population is referred to as "essentially homogeneous," since such populations can comprise more than one variety of plant.

Art Unit: 1638

In claims 8, 10, and 13: the recitation "capable of expressing" in line 1 renders the claim indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation in claims 8 and 10 be replaced with --having--. In claim 13, it is suggested that the recitation "is capable of expressing" be replaced with --has--.

In claim 9: the recitation "further comprising a cytoplasmic or nuclear gene conferring male sterility" renders the claim indefinite. The recitation broadens the scope of its parent claim. The specification does not define plants expressing all the physiological and morphological characteristics of LIZL5 as being male sterile, or as comprising a cytoplasmic or nuclear gene that confers male sterility. It is suggested that the claim be amended to recite that the plant was produced from the plant of claim 8 and to indicate how the cytoplasmic or nuclear gene conferring male sterility was introduced into the plant of claim 8.

In claim 11: the recitation "derived from" renders the claim indefinite. It is not clear how the cells are derived from the recited tissues. It is suggested that the term "derived" be deleted, or be replaced with the term --isolated--.

In claim 12: the recitation, "cells are in the form of protoplasts" renders the claim indefinite, since protoplasts are not cells.

In claims 14 and 17: the recitation, "in accordance with" renders the claim indefinite. It is not exactly clear what this recitation means, making the metes and bounds of the claim unclear.

In claim 19: claim 19 is improperly dependent on claim 18. Claim 19 recites a new process. However, to be properly dependent on claim 18, the claim 19 should recite how the

Art Unit: 1638

process of claim 18 is further limited. It is suggested that claim 19 be amended by replacing the recitation, "further defined as a process of producing hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant," be deleted, and the recitation, --, and said second parent corn plant is a distinct inbred corn plant--, be inserted in line 4 after "PTA-2192."

In claim 25: the recitation "further comprising a single locus conversion" renders the claim indefinite. The recitation broadens the scope of claim 4, for reasons similar to the rejection of claim 9.

In claim 26: the recitation "wherein the single locus was stably inserted into a corn genome" renders the claim indefinite. It is not clear if the corn genome is that of LIZL5 or that of another corn plant.

In claim 28: the recitations, "yield enhancement," "improved nutritional quality," and "enhanced yield stability" are relative terms that have not definite meaning, making the metes and bounds of the claim unclear.

In claims 29 and 39: the recitation "pre-selected DNA" renders the claim indefinite. It is unclear what is meant by "pre-selected," as all isolated DNA molecules can be considered "pre-selected."

In claim 31: the recitation "PEG mediated transformation of protoplasts" renders the claim indefinite. The recitation does not further limit the recitation, "contacting said cells" in claim 29. It is suggested that claim 29 be amended by inserting the recitation, --or protoplasts of said cells-- in line 4 after "said cells."

Art Unit: 1638

In claim 37: the recitation, "preparable," renders the claim indefinite. Is the plant, or is the plant not, prepared by the process of claim 30?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 7, 14-17, and 22-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 02 December 2002 under item 4 for claims 22-28 and 37-39. Applicants traverse the rejection in the papers received 10 April 2003. Applicants' arguments have been fully considered but were not found persuasive.

The claims are broadly drawn towards an essentially homogeneous population of inbred corn seed LIZL5; or inbred corn seed LIZL5 essentially free from hybrid seed; or any hybrid corn seed produced by the process of crossing the inbred corn plant LIZL5 with any second, distinct, inbred corn plant; any hybrid corn plant produced by growing said hybrid corn seed; any inbred corn plant produced by growing seed of inbred corn plant LIZL5, wherein said plant further comprises any single locus conversion, or wherein the single locus was stably inserted into the genome by transformation, or wherein the locus is any dominant or recessive allele; or a method of preparing a transgenic maize cell comprising providing cells of plant LIZL5,

Art Unit: 1638

contacting said cells with any pre-selected DNA; or any fertile transgenic maize plant produced by regenerating a transgenic plant from a cell of LIZL5 that has been contacted with any pre-selected DNA, or seed of said fertile transgenic plant, or a plant grown from said seed and which comprises said pre-selected DNA, and to an inbred corn plant cell having an RFLP genetic marker profile in accordance with the profile in Table 6 or the isozyme type in accordance with the profile in Table 7.

The specification describes the morphological and physiological characteristics, SSR profile, and isozyme profile of inbred corn plant LIZ5 (page 22, lines 2-6; Tables 1 and 2, pages 22-24; page 24, line 15 to page 25, line 18; Table 3, pages 25-27; Table 6, pages 58-60; Table 7, pages 60-61). The specification indicates that a deposit of 2500 seeds of LIZL5 has been made with the American Type Culture Collection, under the Accession No. PTA-2192, under the terms of the Budapest Treaty (amendment to page 27 of the specification, in the paper submitted 19 February 2002, pages 2-3). It is noted that all restrictions to the availability of the deposited seed will be irrevocably removed upon the granting of a patent (Exhibit 1, paper submitted 19 February 2002). The specification also describes morphological traits and an SSR profile of a hybrid plant, designated "7026255," produced by crossing LIZL5 with an inbred maize plant designated "16SCQ2" (page 49, lines 18-24; Table 5, pages 54-55; Table 8, pages 61-63; Table 7). The specification also compares performance data for hybrid 7026255 with other corn plants (page 52, lines 1-3, Table 4, page 53).

However, the specification does not describe any hybrid corn seeds or plants other than the plant designated 7026255. Hybrids produced by crossing LIZL5 with other plants would of course produce plants that do not express the same traits as LIZL5 or 7026255. The descriptions

Art Unit: 1638

of LIZL5 and 7026255 do not provide any information concerning the morphological and physiological characteristics of any other plant. In addition, a written description of each of the RFLP and isozyme markers is not provided. While the markers are named, this is not sufficient to describe them.

The specification also indicates that essentially homogeneous populations of inbred seed can contain other seed besides LIZL5 (page 5, lines 14-22). The specification also indicates that populations of inbred seed can be further defined as being essentially free of hybrid seed (page 6, lines 5-7), which may indicate that populations of inbred seed can also comprise other seed, as discussed above. However, in those populations where LIZL5 seed forms less than 100% of the population, the identity of the remaining seed is unknown, yet the claims encompass all the individuals of the population. The specification does not describe the non-LIZL5 seed of the essentially homogeneous populations, or the hybrids from which LIZL5 seed is "essentially free."

The specification also does not describe LIZL5 plants that further comprise single locus conversions or transgenes. The plants may be altered from LIZL5 in any of its traits. However, the specification does not describe single locus conversions and single transgenes that have the ability to alter any given maize plant trait. For example, single locus conversions or transgenes that govern yield enhancement, waxy starch, or enhanced yield stability are not described. The transgenes, such as those that encode transcription factors, may also affect more than one trait. Descriptions of such transgenic plants are not presented. The claims drawn towards preparing transgenic maize cells are included in this rejection, as all of the products required for the method are not described. Further, methods to make the claimed plants do not provide a

Art Unit: 1638

description of all the morphological and physiological traits of the plants themselves. Given the breadth of the claims encompassing all hybrid corn seeds produced by crossing LIZL5 to any other maize plant, LIZL5 plants comprising any single locus conversion or any transgene, and lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

In the Appeal Brief received 10 April 2003, Applicants again argue that the hybrid seeds and plants of claims 22-24 are described because they have LIZL5 as a parent and that they have inherited half of their genetic material from LIZL5 (appeal brief, paragraph bridging pages 5-6). The Examiner maintains that the claimed hybrids will not have the same morphological and physiological characteristics as LIZL5. LIZL5 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of morphological and physiological characteristics that are different from each other, and which are also different from those expressed by LIZL5. That all hybrids will inherit half of their alleles from LIZL5 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of LIZL5 with any of the traits that it expresses. Further, the claimed hybrids will inherit the other half of their genetic material from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from LIZL5, or their products, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and the epigenetic

Art Unit: 1638

effects of other genes. The fact that any hybrid plant will inherit half of its alleles from LIZL5 then does not provide sufficient description of the morphological and physiological characteristics expressed by each and every hybrid plant.

Applicants also argue that the entire genetic contribution of corn plant LIZL5 is described by way of deposit of seed of LIZL5 with the ATCC, and believe that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants. In support of their argument, Applicants cite the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposited material (appeal brief, paragraph bridging pages 5-6). However, in the patent application considered in that decision, a function was correlated with the structure of the product that was deposited. Here, the functions of the claimed hybrid plant have not been correlated to the half of their genetic material originating from the deposited LIZL5 seed. Further, half of the alleles of the hybrid are inherited from the other parent. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited LIZL5 seed.

Applicants continue, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Applicants argue that here, all of the members of the claimed genus of hybrids having LIZL5 as one parent share the identical feature of having the genetic complement of LIZL5 (appeal brief, page 6, 1<sup>st</sup> full paragraph). However, the function of the product claimed in *Eli Lilly* was known. In the instant

Art Unit: 1638

application, the specification does not describe the function of the claimed hybrids, and does not correlate the function of the hybrids with the structure of the genetic complement of LIZL5.

Furthermore, the genetic complement of the other unknown parent has not been described, and hence Applicant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred LIZL5 with any and all other inbred or hybrid corn plants.

In response to the issue raised in the previous Office action, that other plants may share genetic marker data and that primer sequences are not described, Applicants argue that no effort was made to show that any substantial number of marker loci actually are shared by other plants (appeal brief, paragraph bridging pages 6-7). However, the specification shows that at least two other inbred corn plants share many of the same loci (see Table 6). Further, the specification does not explain why the SSR data of inbreds 01IBH2 and MM402A were chosen for comparison with that of LIZL5 in Table 6, how related the inbreds are to LIZL5, and hence how useful the SSR markers are for distinguishing maize lines. Also, the specification does not mention anything concerning the traits expressed by the 01IBH2 and MM402A plants, and how similar those traits are to the combination of traits expressed by LIZL5.

Applicants also again argue that the description of the claimed hybrids is provided by way of a detailed description of hybrid 7026255, produced using LIZL5 as one inbred parent (appeal brief, page 7, 1<sup>st</sup> full paragraph). However, the Examiner maintains that the description of corn plant 7026255 does not describe the morphological and physiological traits of all other corn plants that can be produced by crossing LIZL5 to any other corn plant. One skilled in the art cannot identify all of the morphological and physiological characteristics of corn plant

Art Unit: 1638

7026255 that also definitely will be expressed by all other members of the genus, nor can one identify the characteristics that will be different. Further, while hybrid 7026255 has inherited the SSR marker profile of LIZL5, the specification does not describe the traits that are correlated with these markers. The traits expressed by 702655 are not solely due to the presence of the alleles associated with the SSR markers, or the genetic contribution of LIZL5.

Regarding claims drawn towards corn plant LIZL5 containing single locus conversions: Applicants appear to be arguing that the specification describes such plants, simply because the definition of "single locus converted plants" provided in the specification indicates that such plants possess essentially all of the desired morphological and physiological characteristics of plant LIZL5 in addition to the characteristics conferred by the single locus transferred (appeal brief, paragraph bridging pages 7-8). However, the specification does not describe the characteristics expressed by the claimed plants. The specification does not describe any and all single locus conversion traits, nor the source of said traits. The traits conferred by the single locus may change one or more of the traits expressed by LIZL5. Further, the description of plants that express "essentially" all of the "desired" characteristics of LIZL5 are not described. Further, the term "essentially" in the definition for "single converted plant" indicates that, in addition to the trait conferred by the single transferred locus, the plant does not have to express every one of the traits that the specification provides in its description of LIZL5. The definition also indicates that the plants only have to possess the "desired" characteristics of LIZL5, not all of them. Backcross converted plants that do not have all of the morphological and physiological traits of LIZL5 are not described by the specification, or the deposit of LIZL5 seed.

Art Unit: 1638

Applicants cite *In re Gosteli* for indicating that the written description requirement does not require an applicant to describe exactly the subject matter claimed, but that the description must clearly allow persons of ordinary skill in the art to recognize what is claimed (appeal brief, paragraph bridging pages 7-8). However, the specification does not describe the traits expressed by all of the claimed plants, nor what set of traits are present in all of the claimed plants to allow persons of ordinary skill in the art to recognize the claimed plants. As discussed, the specification does not describe plants that express only some or "desired" traits that are expressed by LIZL5, or how to distinguish such plants from LIZL5. Further, single loci, for example those encoding a transcription factor, may affect one or more traits expressed by LIZL5. The claimed plant then would not express all of the traits of LIZL5. Such plants are not described by the specification.

Applicants also argue that pages 29-32 provide numerous transgenes or conventional single locus traits (appeal brief, page 8, last paragraph). However, neither the specification nor the references cited in the specification describes single genes or loci that confer yield enhancement or yield stability. If such single loci do not exist, Applicants cannot be in possession of those claimed plants. The claims broadly encompass plant LIZL5 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Applicant cannot be in possession of plants further comprising single locus conversions that have yet to be identified.

Applicants argue that transgenic single locus conversions are described on page 30, including those created using various transformation methods (appeal brief, page 9, 1<sup>st</sup> full paragraph). However, methods to produce a product do not describe the product itself.

Art Unit: 1638

Applicants argue that every possible transgene or single locus conversion that could be introduced into corn plant LIZL5 is not required under written description, and cite *In re Baird* as support (appeal brief, paragraph bridging pages 9-10). However, the issue in that decision concerned the motivation to combine teachings in an obviousness rejection, not written description.

5. Claims 25-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of transforming LIZL5 when the transgene is known in the art and whose effect when expressed in transformed plants is known, does not reasonably provide enablement for the methods of transforming LIZL5 with all transgenes, or for producing LIZL5 plants comprising single locus conversions by backcrossing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to inbred corn plant LIZL5 further comprising a single locus conversion; or to any method of preparing transgenic LIZL5 cells comprising contacting cells of inbred corn plant LIZL5 with any pre-selected DNA, having any function; or wherein said method further comprises regenerating a fertile transgenic plant; or a fertile transgenic plant produced by said method; or seed of said transgenic plant; or a plant grown from said seed.

The specification teaches single locus converted plants are developed by a plant breeding technique called backcrossing, wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the single locus transferred into the inbred via backcrossing (page 27, line 18 to page 29, line 2).

Art Unit: 1638

However, the specification does not teach any LIZL5 plants comprising single locus conversions produced by backcrossing. It is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art.

Art Unit: 1638

The specification also teaches that single loci may be introduced into LIZL5 plants by transformation (page 29, lines 4-5; page 30, line 23 to page 31, line 30).

However, the specification does not enable transforming LIZL5 cells with all transgenes. As broadly interpreted, the claimed plants and method encompass introducing any type of transgene into LIZL5, including those that have not been isolated at the time the application was filed. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Further, if the effect of transgene expression in LIZL5 is unknown, one skilled in the art would not know how to use the transformed plant. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Furtherstill, the effects of transgene expression on the traits expressed by untransformed LIZL5 are unknown. The specification does not teach one how to use a transformed LIZL5 plant if all of the morphological and physiological traits of LIZL5 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

6. Claims 1 and 4-6 are allowed. Claims 2, 3, and 7-39 are rejected.

Art Unit: 1638

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
ASHWIN D. MEHTA, PH.D.  
PATENT EXAMINER

July 14, 2003